sanofi aventis
Because health matters

07 January 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-D-0520

Draft Guidance for Industry on Potency Tests for Cellular and Gene Therapy Products

Dear Sir/Madam:

Sanofi aventis U.S. welcomes the opportunity to comment on the above-referenced draft document entitled *"Draft Guidance for Industry on Potency Tests for Cellular and Gene Therapy Products,"* and suggests the following comments:

SPECIFIC COMMENTS:

1. **Section III.C, Page 7, end of 1st paragraph:**
"This could necessitate that you stress the product (i.e., show that the assay can detect an inactive or degraded product) and perform sufficiently controlled studies (see Section IV.)."

Comment:

Suggest the addition of the following text at the end of the sentence: "or employ a validated analytical assay."

Rationale:

ICH Guidance on analytical method validation incorporates specificity of method into validation. These industry best practices are implied when one refers to a validated analytical method.

sanofi-aventis U.S., Corporate Regulatory Affairs Office, 4520 East West Highway, Suite 210, Bethesda, MD 20814
Tel: (301) 771-4261 - www.sanofi-aventis.us

2. Section IV.B, Page 11, paragraph 2:
"Because you will use reference materials at various stages of product development and characterization, you should subject them to stability studies in parallel with your product stability studies (Ref. 7)."

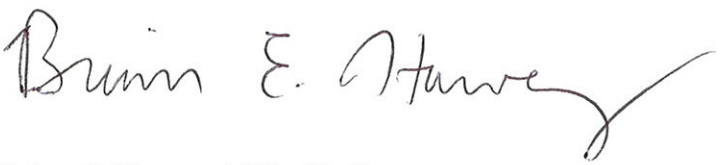
Comment:
Add the following text to the end of the sentence: "…stability studies, and assign appropriate retest or expiration dates."

Rationale:

FDA Guidance for Bioanalytical Method Validation as well as industry practice, both warrant the use of a well characterized reference material. The stability measurements alone would not satisfy the definition of "well characterized" if the material did not receive either an expiration or retest dating period.

Sanofi-aventis appreciates the opportunity to comment on the **Draft Guidance for Industry on Potency Tests for Cellular and Gene Therapy Products** and hopes the comments provided are useful in the guidance development process.

Sincerely,



Brian E. Harvey, M.D., Ph.D.
Vice President
Regulatory Policy